



# **Privacy Impact Assessment**

## **Laboratory Information Management System (LIMS)**

***Revision: 1.9***

***Food Safety and Inspection  
Service (FSIS)***

***Date: June 28, 2010***



## Document Information

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Revision History			
Revision	Date	Author	Comments
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1.1	May 1, 2009	Veronica Cuello	Changed to 2008 Template
1.2	May 4, 2009	Veronica Cuello	Christopher Douglas revision
1.3	May 19, 2009	Susan Knowler	Edits to include subsystems
1.4	July 27, 2009	Veronica Cuello	Added Privacy Officer suggestions (John "Major" Nelson)
1.5	July 28, 2009	Susan Knowler	Additional edits
1.6	July 29, 2009	Veronica Cuello	Reviewed Privacy Officer comments
1.7	August 5, 2009	Veronica Cuello	Added Christopher Douglas comments
1.8	August 5, 2009	Susan Knowler	Reviewed Christopher Douglas comments
1.9	June 28, 2010	Christopher Douglas	Updated document to address reviewer's comments.

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# 1 System Information

System Information	
Agency:	Food Safety and Inspection Service
System Name:	Laboratory Information Management System (LIMS)
System Type:	<input checked="" type="checkbox"/> Major Application <input type="checkbox"/> General Support System <input type="checkbox"/> Non-major Application
System Categorization (per FIPS 199):	<input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low
Description of System:	<p>The LIMS is a database that will provide complete tracking of a sample from the time it is received at the laboratory until the results are completed. LIMS will maintain sample tracking so the FSIS may maintain its mission of supplying a safe food supply to the Nation's population</p> <p>ISO 17025, which applies to LIMS, is a policy decision that FSIS made to increase the credibility of its lab analyses and be able to have the analysis results be able to withstand legal challenge. The LIMS functions primarily to capture and store data related to samples that are processed and analyzed in the Field Services Laboratories (FSL). The LIMS performs additional functions to maintain laboratory data integrity and to permit data reporting, analysis, and availability to authorized users.</p>
Who owns this system? (Name, agency, contact information)	Patrick McCaskey, Executive Associate for Laboratory Services, FSIS, Office of Public Health Science, Russell Research Center, Athens, GA 706-546-3422 <a href="mailto:Patrick.Mccaskey@fsis.usda.gov">Patrick.Mccaskey@fsis.usda.gov</a>
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Who completed this document? (Name, agency, contact information)	<p>Frank Niagro, Lead Microbiologist (Laboratory Data Management Specialist), FSIS, Office of the Chief Information Officer, Russell Research Center, Athens, GA 706-546-3560 <a href="mailto:Frank.Niagro@fsis.usda.gov">Frank.Niagro@fsis.usda.gov</a>.</p> <p>Veronica Cuello, ISSO Representative, FSIS, Office of the Chief Information Officer, ISSP, 1255 22<sup>nd</sup> Street, N.W., Washington DC 20250-3700, <a href="mailto:Veronica.Cuello@fsis.usda.gov">Veronica.Cuello@fsis.usda.gov</a></p> <p>Susan Knower, Branch Chief, FSIS, Office of the Chief Information Officer, 901 D St. SW Washington DC 20024 <a href="mailto:susan.knower@fsis.usda.gov">susan.knower@fsis.usda.gov</a></p>

## 2 Data Information

### 2.1 Data Collection

No.	Question	Response
1	Generally describe the data to be used in the system.	Laboratory sample schedule, collection, and analysis data for meat, poultry, and egg product samples analyzed to support public health regulatory decisions.  In LIMS, employee identification is collected to identify who is responsible for the entry of any particular data item, and to provide role-based user access.
2	Does the system collect Social Security Numbers (SSNs) or Taxpayer Identification Numbers (TINs)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 3.
2.1	State the law or regulation that requires the collection of this information.	N/A
3	Is the use of the data both relevant and necessary to the purpose for which the system is being designed? In other words, the data is absolutely needed and has significant and demonstrable bearing on the system's purpose as required by statute or by Executive order of the President.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  For LIMS, ISO 17025 accreditation and GAMP5 guidelines require the use of electronic signatures to identify the user responsible for the entry or update of a data item.
4	Sources of the data in the system.	Role-based user tables
4.1	What data is being collected from the customer?	N/A LIMS has no customers outside FSIS.
4.2	What USDA agencies are providing data for use in the system?	FSIS
4.3	What state and local agencies are providing data for use in the system?	None
4.4	From what other third party sources is data being collected?	None
5	Will data be collected from sources outside your agency? For example, customers, USDA sources (i.e., NFC, RD, etc.) or Non-USDA sources.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 6.  The only personally identifiable information is of FSIS employees.
5.1	How will the data collected from customers be verified for accuracy, relevance, timeliness, and completeness?	N/A LIMS has no customers outside FSIS.
5.2	How will the data collected from USDA sources be verified for accuracy, relevance, timeliness, and completeness?	LIMS uses two-factor authentication, utilizing SafeNet iKey tokens, to accurately identify users.



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No.	Question	Response
5.3	How will the data collected from non-USDA sources be verified for accuracy, relevance, timeliness, and completeness?	N/A LIMS has no users outside FSIS.

## 2.2 Data Use

No.	Question	Response
6	Individuals must be informed in writing of the principal purpose of the information being collected from them. What is the principal purpose of the data being collected?	Positive verification of personal identity for electronic signatures on laboratory records. This is accomplished by two-factor authentication, utilizing SafeNet iKey tokens and user login ID and password.  Only FSIS staff or authorized FSIS contractors have access.  This data is collected to meet ISO 17025 accreditation and GAMP5 guidelines which require the use of electronic signatures to identify the user responsible for the entry or update of a data item.
7	Will the data be used for any other purpose?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 8.
7.1	What are the other purposes?	N/A
8	Is the use of the data both relevant and necessary to the purpose for which the system is being designed? In other words, the data is absolutely needed and has significant and demonstrable bearing on the system's purpose as required by statute or by Executive order of the President.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No For LIMS, ISO 17025 accreditation and GAMP5 guidelines require the use of electronic signatures to identify the user responsible for the entry or update of a data item.
9	Will the system derive new data or create previously unavailable data about an individual through aggregation from the information collected (i.e., aggregating farm loans by ZIP codes in which only one farm exists.)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 10.
9.1	Will the new data be placed in the individual's record (customer or employee)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.2	Can the system make determinations about customers or employees that would not be possible without the new data?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.3	How will the new data be verified for relevance and accuracy?	N/A
10	Individuals must be informed in writing of the routine uses of the information being collected from them. What are the intended routine uses of the data being collected?	Positive verification of personal identity for electronic signatures on laboratory records.

No.	Question	Response
11	Will the data be used for any other uses (routine or otherwise)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 12.
11.1	What are the other uses?	N/A
12	Automation of systems can lead to the consolidation of data – bringing data from multiple sources into one central location/system – and consolidation of administrative controls. When administrative controls are consolidated, they should be evaluated so that all necessary privacy controls remain in place to the degree necessary to continue to control access to and use of the data. Is data being consolidated?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 13.
12.1	What controls are in place to protect the data and prevent unauthorized access?	N/A
13	Are processes being consolidated?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 14.
13.1	What controls are in place to protect the data and prevent unauthorized access?	N/A

## 2.3 Data Retention

No.	Question	Response
14	Is the data periodically purged from the system?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 15.
14.1	How long is the data retained whether it is on paper, electronic, in the system, or in a backup?	Permanently
14.2	What are the procedures for purging the data at the end of the retention period?	N/A
14.3	Where are these procedures documented?	N/A
15	While the data is retained in the system, what are the requirements for determining if the data is still sufficiently accurate, relevant, timely, and complete to ensure fairness in making determinations?	Supervisors review their employees' analytical results before authorizing release of the results. In addition, analysts have to be certified in the analyses they perform and have to be re-certified periodically according to the Laboratory Quality Manual, rev. 11.
16	Is the data retained in the system the minimum necessary for the proper performance of a documented agency function?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No For LIMS, ISO 17025 accreditation and GAMP5 guidelines require the use of electronic signatures to identify the user responsible for the entry or update of a data item.

## 2.4 Data Sharing

No.	Question	Response
17	Will other agencies share data or have access to data in this system (i.e., international, federal, state, local, other, etc.)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 18.
17.1	How will the data be used by the other agency?	N/A
17.2	Who is responsible for ensuring that the other agency properly uses the data?	N/A
18	Is the data transmitted to another agency or an independent site?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 19.
18.1	Is there appropriate agreement in place to document the interconnection and ensure that the PII and/or Privacy Act data is appropriately protected?	N/A
19	Is the system operated in more than one site?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No – If NO, go to question 20. LIMS is operated in the FSIS laboratories located in Athens, GA, St. Louis, MO, and Alameda, CA. Data is replicated between labs using IPSEC and there are preconfigured SQL Server replication profiles that perform integrity checks on the replicated data.
19.1	How will consistent use of the system and data be maintained in all sites?	Data is replicated between labs using IPSEC and there are preconfigured SQL Server replication profiles that perform integrity checks on the replicated data.

## 2.5 Data Access

No.	Question	Response
20	Who will have access to the data in the system (i.e., users, managers, system administrators, developers, etc.)?	System administrators, system users, system developers, and ISO accrediting agency auditors.
21	How will user access to the data be determined?	Role- and group-based security. Access is defined by the system owner.
21.1	Are criteria, procedures, controls, and responsibilities regarding user access documented?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Laboratory employees must complete "Personnel Training" according to SOP LW-0001.05, prior to access and annually.
22	How will user access to the data be restricted?	Role-based permissions in the application and on the database server (DBAs and server admins). Windows-based security within reporting services on the Reporting Server.

No.	Question	Response
22.1	Are procedures in place to detect or deter browsing or unauthorized user access?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No The data is not online and only users authorized by role and authenticated using SafeNet iKey tokens have access.
23	Does the system employ security controls to make information unusable to unauthorized individuals (i.e., encryption, strong authentication procedures, etc.)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Data is replicated between labs using IPSEC.

## 2.6 Customer Protection

No.	Question	Response
24	Who will be responsible for protecting the privacy rights of the customers and employees affected by the interface (i.e., office, person, departmental position, etc.)?	FSIS, OPHS, Program Analysts for the Western Lab (Alameda), the Eastern Lab (Athens), the Food Emergency Response Network (Athens, GA), and the Executive Associate for Laboratory Services (Athens, GA)
25	How can customers and employees contact the office or person responsible for protecting their privacy rights?	<p>The Program Analysts are co-located with the affected employees and can be contacted in person, via phone, or E-Mail.</p> <p>Individuals who have reason to believe that this system might have records pertaining to them should write to the USDA FOIA Officer - Room 209-A, Jamie Whitten Bldg. 1400 Independence Avenue, S.W. Washington, D.C. 20250-0103. Personnel in that division will then forward your request to the USDA agency that they believe is most likely to maintain the records you are seeking. The individual must specify that he or she wishes the records of the system to be checked. At a minimum, the individual should include: name; date and place of birth; current mailing address and zip code; signature; and a brief description of the circumstances that caused the creation of the record (including the city and/or country and the approximate dates) which gives the individual cause to believe that this system has records pertaining to him or her.</p>
26	A "breach" refers to a situation where data and/or information assets are unduly exposed. Is a breach notification policy in place for this system?	<input checked="" type="checkbox"/> Yes – If YES, go to question 27. <input type="checkbox"/> No USDA PII policy
26.1	If NO, please enter the Plan of Action and Milestones (POA&M) number with the estimated completion date.	N/A

No.	Question	Response
27	<p>Consider the following:</p> <ul style="list-style-type: none"> <li>Consolidation and linkage of files and systems</li> <li>Derivation of data</li> <li>Accelerated information processing and decision making</li> <li>Use of new technologies</li> </ul> <p>Is there a potential to deprive a customer of due process rights (fundamental rules of fairness)?</p>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 28.
27.1	Explain how this will be mitigated?	N/A
28	How will the system and its use ensure equitable treatment of customers?	LIMS has no customers outside FSIS.
29	Is there any possibility of treating customers or employees differently based upon their individual or group characteristics?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No – If NO, go to question 30
29.1	Explain.	FSIS lab-wide work instructions and SOPs should address equitable treatment. See Laboratory Quality Manual, revision 11, 6/01/2009.

### 3 System of Record

No.	Question	Response
30	Can the data be retrieved by a personal identifier? In other words, does the system actually retrieve data by the name of an individual or by some other unique number, symbol, or identifying attribute of the individual?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No – If NO, go to question 31
30.1	How will the data be retrieved? In other words, what is the identifying attribute (i.e., employee number, social security number, etc.)?	The data could be queried from the database based on the user's name, userid, or analyst code, but there is no requirement to do that.
30.2	Under which Systems of Record Notice (SORN) does the system operate? Provide number, name, and publication date. (SORNs can be viewed at <a href="http://www.access.GPO.gov">www.access.GPO.gov</a> .)	<p>The system does not operate under a SORN since the retrieval of an individual's information "CAN" be done but is not a routine function of the system. The potential to retrieve an individual's information does not require a SORN nor would pulling up a record as part of a DB administrative function require one as well.</p> <p>However, if the analysts' information is released routinely to entities outside of USDA, that would require a SORN be established.</p>
30.3	If the system is being modified, will the SORN require amendment or revision?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

## 4 Technology

No.	Question	Response
31	Is the system using technologies in ways not previously employed by the agency (e.g., Caller-ID)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No – If NO, the questionnaire is complete. LIMS utilizes SafeNet iKey tokens and logon id and password for two-factor authentication.
31.1	How does the use of this technology affect customer privacy?	LIMS has no customers outside FSIS.



## 5 Completion Instructions

Upon completion of this Privacy Impact Assessment for this system, the answer to OMB A-11, Planning, Budgeting, Acquisition and Management of Capital Assets, Part 7, Section E, Question 8c is:

**1. Yes.**

PLEASE SUBMIT A COPY TO THE OFFICE OF THE ASSOCIATE CHIEF  
INFORMATION OFFICE FOR CYBER SECURITY.



## Privacy Impact Assessment Authorization

### Memorandum

I have carefully assessed the Privacy Impact Assessment for the

Laboratory Information Management System (LIMS)

This document has been completed in accordance with the requirements of the E-Government Act of 2002.

We fully accept the changes as needed improvements and authorize initiation of work to proceed. Based on our authority and judgment, the continued operation of this system is authorized.

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Dr Patrick McCaskey  
Information System Owner/Project Manager

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Date

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Elamin Osman  
Information System Security Program Manager

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Date

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Janet Stevens  
Chief Information Officer

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Date